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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/435,576	CHEN ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,18,19,21,22,25-54,57-71 and 76-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,18,19,21,22,25-54,57-71 and 76-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Request for Continued Examination received on September 24, 204 is acknowledged.

Claims **1-13,18, 19, 21, 22, 25-54, 57-71 and 76-81** are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 9, 21-22, 25-26, and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites "substantially complete release" which is indefinite since it is unclear if the drug is completed or substantially released. The specification does not define the limits of this terminology.

Claims 9 and 47 recite the term "a derivative or lovastatin and active metabolite of lovastatin" which is rendered indefinite since one of ordinary skill in the art would not know the metes and bounds of this terminology. Further, the specification does not define what these derivatives encompass.

Claim 21, 22, and 25-26 depend on a cancelled claims and thus the scope of these claims are unclear.

Claim 71 recites "at the same time nor increasing the bioavailability of lovastatin acid, active or total inhibitors" which is indefinite since it is unclear what "active or total inhibitors" encompass or intends to limit. What is the "active" and "inhibitor" that applicant is decreasing?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-13, 18-19, 21-22, 25-26, 28-29, 33-37, 39, 41, 43, 76-77, and 80are rejected under 35 U.S.C. 102(b) as being anticipated by Cheng et al, Evaluation of Sustained/Controlled Release dosage forms of 3-Hydroxy-3-Methylglutaryl-Coenzyme A (HMG-CoA) Reductase Inhibitors in Dogs and Humans, Pharmaceutical Research (19923), 10:1683-1687.

Cheng et al disclose controlled release device containing lovastatin and a sustained release matrix. Cheng discloses that lovastatin hydrolyzes in vivo to form its corresponding beta-hydroxyacid, which are potent inhibitors of HMG-CoA reductase. See page 1683. Further, Cheng discloses that the liver, the target organ, more efficiently extracts lovastatin and simvastatin than their corresponding beta-hydroxyacid. Thus, the use of controlled release device allows for an equal or better therapeutic value. Table V teaches the pharmokinetics of simovastin administered to humans. See page 1687. Table II teaches the total HMG-CoA reductase inhibitors (lovastatin and its acid form) pharmokinetic parameters (AUC, the Cmax, Tmax, AUC ratio of 0.94, 1.03, 0.43, and 0.52, and Cmax ratio of 0.66, 0.64, 0.16, and 0.13) in dogs receiving various lovastatin dosage forms. See page 1685. CRS14 formulation provides for a Tmax of 7.5 ± 1.2 hours for an 80mg lovastatin oral dose.

Note that applicant has not defined "about 10" in the specification; thus Cheng's formulation that yields a Tmax of 8.7 (with the standard deviation) reads on this limitation. Moreover, it is the examiner's position that if the Tmax is the same, then the pharmokinectics will be the same.

Further, the intended use recitation, "administered to humans" does not hold patentable weight in product claims.

Claims 1-13,18, 19, 21, 22, 25-54, 57-71 and 76-81 are rejected under 35 U.S.C. 102(b) as being anticipated by Alberts et al (5,376,383).

Alberts discloses a method of lowering plasma cholesterol levels by administering to a subject a time-controlled drug-delivery device containing a water-soluble HMG-CoA reductase inhibitor (lovastatin, pravastatin, etc). Alberts discloses that using a sustained or controlled release provides for a single dose to yield an equivalent or improved effect as that of a rapid release formulation (col. 1, lines 39-50 and abstract). Additionally, the formulation lowers the amount of peak drug plasma concentration in the blood; thus the potential side effects of the drug are reduced. The controlled release is over a 6 to 24 hour period (col. 2, line 63). Alberts discloses that this controlled release can be achieved by a variety of procedures known to those skilled in the art and discloses various controlled released matrices in the examples. The procedures suitable for the invention are diffusion-controlled systems, osmotic devices, dissolution controlled matrices, and erodible/degradable matrices (col. 3, lines 1-2). Lastly it should be noted that lovastatin hydrolyzes in vivo to form its acid form, lovastatin acid.

* That although the prior art does explicitly state the instant functional limitations, it is the examiner's position that the instant functional limitation is inherent since Albert's example

10 provides a release rate over an 18 hour period. Thus, the Tmax would inherently fall within instant range. The recitation of a newly discovered function inherently possessed by the prior art, does not make distinguish it form the prior art. Further, it is the applicant's burden to prove otherwise. See In re Best, 195 USPQ 430 (CCPA 1977).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13,18, 19, 21, 22, 25-54, 57-71 and 76-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alberts et al (4,997,658) in view of Chen et al (5,558,879).

Alberts discloses a method of lowering plasma cholesterol levels by administering to a subject a time-controlled drug-delivery device containing an HMG-CoA reductase inhibitor (lovastatin, pravastatin, etc). Alberts discloses that using a sustained or controlled release provides for a single dose to yield an equivalent or improved effect as that of a rapid release formulation (col. 1, lines 39-50 and abstract). Additionally, the formulation lowers the amount of

peak drug plasma concentration in the blood; thus the potential side effects of the drug are reduced. The controlled release is over a 6 to 24 hour period (col. 2, line 63). Alberts discloses that this controlled release can be achieved by a variety of procedures known to those skilled in the art. The procedures suitable for the invention are diffusion-controlled systems, osmotic devices, dissolution controlled matrices, and erodible/degradable matrices (col. 3, lines 1-2). Alberts provides formulations for different controlled release devices on column 3 wherein different insoluble walls, osmotic solutes, and resins are added to modulate the release of the active. Lastly it should be noted that lovastatin hydrolyzes in vivo to form its acid form, lovastatin acid.

It is unclear if the prior art teaches the instant functional limitations; however Alberts teaches the use of any controlled device that provides an extended release over 6 to 24 hours.

Chen et al teach a once-a-day controlled release formulation to provide extended release in order to maintain therapeutic serum levels of medicaments and to minimize the effects of missed dose of drugs caused by lack of patient compliance. See column 1, lines 5-14. Chen et al teach a once daily pharmaceutical tablet having a 1) compressed core contains a medicament, a water-soluble osmotic compound, and one or more osmotic polymers, and 2) a dual layer membrane coating. The compressed core provides for the sustained release of a medicament over a 24-hour period of time. Figure 1 teaches the instant drug dissolution time and Figure 6 teaches a Tmax of the compressed core medicament of approximately 8.5 hours, which reads on *about* 10 hours. Chen teaches the use of various water-soluble medicaments may be utilized. Chen teaches the inventive controlled device provides for an improved controlled release device since

it avoids the need to have a separate push layer as seen in the prior art and provides a single component core. See column 1 to 2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the teaching of Chen et al and utilize Chen's controlled device. One would have been motivated to do so since Chen provides a once-a-day controlled device that maintains the therapeutic levels of the drug to minimize the side effects of missed doses. Therefore, it is prima facie obvious to combine Alberts teaching that HMG-CoA reductase inhibitor benefit form once-a-day administration provided by extended release tablets that maintain the drug serum level for 6 to 24 hours and combine that teaching with Chen et al, who teaches a once-a-day controlled release device.

Claims 1-13,18, 19, 21, 22, 25-54, 57-71 and 76-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,837,379 to Chen et al.

Chen et al disclose a once daily pharmaceutical tablet having a 1) compressed core contains a medicament, a water-soluble osmotic compound, and one or more osmotic polymers, and 2) a membrane coating containing a water insoluble pharmaceutically acceptable polymer and an enteric polymer. See abstract. Although nifedipine, Chen teaches various water-insoluble medicaments that may be utilized, including instant lovastatin. See column 2, line 64. The composition may additionally have dispersants, lubricants, dyes, and other additives that are conventionally utilized in the art. See column 5, lines 63-65. More specifically, Chen et al teach the medicament granules contain nifedipine, povidone (osmotic polymer), lactose (osmotic agent), and sodium lauryl sulfate (surfactant). The granules are compressed with lactose, Polyox WSR, and Myvaplex and coated with a color coating contains dye, sodium chloride, and water.

The color coating is coated with a sustained release coating; followed by an enteric coating containing HPMC phthalate, pore forming agent, talc, and plasticizer. See examples. Lastly it should be noted that lovastatin hydrolyzes in vivo to form its acid form, lovastatin acid.

Chen does not exemplify lovastatin in the controlled release device nor specify the instant functional limitations.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Chen et al and include the instant lovastatin in the controlled release dosage form. One would have been motivated to do so since Chen teaches a variety of medicaments that would benefit from the use of the instant controlled release formulation and teaches the instant active as one of the suitable medicaments. Therefore, one could reasonably expect similar results by including lovastatin in Chen's controlled release device.

Furthermore, it is the examiner position that the instant controlled release device would meet the instant functional limitations since Chen's controlled release device is similar in structure and formulation to applicant's dosage form described in the specification; in particular Table 1. Therefore, it is the examiner's position that both would function similarly if not the same since the structures of the instant invention and that of the prior art are the same.

Claims 48-50, 58-59, 62-63, 65-66, 68-70, 71, 78-79, and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al, Evaluation of Sustained/Controlled Release dosage forms of 3-Hydroxy-3-Methylglutaryl-Coenzyme A (HMG-CoA) Reductase Inhibitors in Dogs and Humans, Pharmaceutical Research (19923), 10:1683-1687.

Cheng et al teach controlled release device containing lovastatin and a sustained release matrix. Cheng discloses that lovastatin hydrolyzes in vivo to form its corresponding beta-

hydroxyacid, which are potent inhibitors of HMG-CoA reductase. See page 1683. Further, Cheng discloses that the liver, the target organ, more efficiently extracts lovastatin and simvastatin than their corresponding beta-hydroxyacid. Thus, the use of controlled release device allows for an equal or better therapeutic value. Table II teaches the total HMG-CoA reductase inhibitors (lovastatin and its acid form) pharmokinetic parameters (AUC, the Cmax, Tmax, AUC ratio of 0.94, 1.03, 0.43, and 0.52, and Cmax ratio of 0.66, 0.64, 0.16, and 0.13) in dogs receiving various lovastatin dosage forms. See page 1685. CRS14 formulation provides for a Tmax of 7.5 ± 1.2 hours. Table V teaches the pharmokinetics of simovastin administered to humans. See page 1687.

Cheng et al does not specify the pharmokinetics of lovastatin in humans.

Although Cheng utilizes an animal model, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Alberts et al and apply the disclosure to treat humans with the controlled release dosage form to provide for similar pharmokinetic parameters. One would have been motivated to do so since it is conventional in the pharmaceutical industry and its research to draw conclusions from animal models and apply them to humans. Furthermore, Cheng teaches the administration of the dosage forms to humans and dogs, thus one of ordinary skill in the art can ascertain that the controlled release form will also provide similar pharmokinetics in humans. Thus, absent unexpected results demonstrating that controlled release devices work differently in dogs versus humans, it is the examiner's position that Cheng teaches a similar device, which would yield similar functional limitations.

Claims 1-13,18, 19, 21, 22, 25-48, 70-71, 76-77, and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klimistra et al (5,668,134).

Klimistra teaches a method for preventing and reducing phototoxicity reactions and photosensitivity. Medications that cause photosensitivity are formulated into a once-a-day dose by method known in the art, and administered during the evening or early morning. See column 15, lines 24-35. Thus, the peak serum levels are not during the daylight hours. See column 22, lines 25-32. Klimistra teaches a variety of drugs that have been documented with photosensitive reactions include lovastatin and pravastatin and thus are suitable drugs for the invention. See column 13, line 33 and column 14, line 11. The medications may be available in oral dosages containing a wide variety of dosages such as 10 mg, 20mg, as so forth. See column 15, lines 15-20. Table 16 teaches lomefloxacin plasma concentrations wherein the Tmax is 16 hours.

Klimistra does not exemplify the instant HMG-CoA reductase inhibitors or teach them for a method of reducing cholesterol serum levels.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Klimistra et al and include the instant lovastatin or pravastatin in the controlled release dosage form. One would have been motivated to do so since Klimistra teaches a variety of medicaments that would benefit from the use of a once-a-day dosage form that provides a peak serum levels after daylight hours, i.e. a Tmax of 16 hours or so. Moreover, it is the examiner's position that if the Tmax is the same as the instant invention, then the pharmokinectics will be the same or similar.

Claims 48-54, 57-69, 78-79 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klimistra et al (5,668,134) in view of Alberts et al (4,997,658).

Klimistra teaches a method for preventing and reducing phototoxicity reactions and photosensitivity. Medications that cause photosensitivity are formulated into a once-a-day dose by method known in the art, and administered during the evening or early morning. See column 15, lines 24-35. Thus, the peak serum levels are not during the daylight hours. See column 22, lines 25-32. Klimistra teaches a variety of drugs that have been documented with photosensitive reactions include lovastatin and pravastatin and thus are suitable drugs for the invention. See column 13, line 33 and column 14, line 11. The medications may be available in oral dosages containing a wide variety of dosages such as 10 mg, 20mg, as so forth. See column 15, lines 15-20. Table 16 teaches lomefloxacin plasma concentrations wherein the Tmax is 16 hours.

Klimistra does not teach the instant lovastatin or pravastatin for a method of reducing cholesterol serum levels.

Alberts discloses a method of lowering plasma cholesterol levels by administering to a subject a time-controlled drug-delivery device containing an HMG-CoA reductase inhibitor (lovastatin, pravastatin, etc). Alberts discloses that using a sustained or controlled release provides for a single dose to yield an equivalent or improved effect as that of a rapid release formulation (col. 1, lines 39-50 and abstract). Additionally, the formulation lowers the amount of peak drug plasma concentration in the blood; thus the potential *side effects* of the drug are reduced. The controlled release is over a 6 to 24 hour period (col. 2, line 63). Alberts discloses that this controlled release can be achieved by a variety of procedures known to those skilled in the art. The procedures suitable for the invention are diffusion-controlled systems, osmotic devices, dissolution controlled matrices, and erodible/degradable matrices (col. 3, lines 1-2). Alberts provides formulations for different controlled release devices on column 3 wherein

different insoluble walls, osmotic solutes, and resins are added to modulate the release of the active. Lastly it should be noted that lovastatin hydrolyzes in vivo to form its acid form, lovastatin acid.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Klimistra and Alberts and utilize Klimistra's lovastatin/pravastatin dosage form to reduce cholesterol serum levels in hums. One would have been motivated to do so since Alberts teaches the instant HMG-CoA reductase inhibitors are effective in reducing plasma cholesterol levels.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13,18, 19, 21, 22, 25-54, 57-71 and 76-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,916,595 and 6,485,748. Although the conflicting claims are not identical, they are not patentably distinct from each other because since they encompass similar subject matter.

US '595 is directed to a controlled release oral solid dosage form containing hydroxyl substituted naphthalene compound selected from the group consisting of mevatatin, pravastatin, simvastatin, and lovastatin. The dosage form contains a compressed core containing the medicament and an outer coating layer. US '748 is also directed to a controlled release oral solid dosage form containing a compressed core with a slightly soluble medicament and a membrane coating. The specification defines lovastatin as a drug that is slightly soluble.

Instant application is directed to a controlled release oral solid dosage form for the reduction of serum cholesterol levels containing lovastatin and a controlled release carrier wherein the said dosage form has certain functional limitations upon consumption of the said dosage form.

Although US patent does not claim the functional limitation as seen in instant application, the controlled dosage form of US patent '595 would function in a similar manner as instantly claimed dosage form since both claim the same drug and the same controlled release structure. Although US patent '748 recites a generic slightly water-soluble drug, the specification defines lovastatin as a drug that falls within this category. Thus, the instant application and US patents are related genus-species, wherein instant application recites the species and falls within the generic scope of the US patents '595 and '748.

Claims 1-13,18, 19, 21, 22, 25-54, 57-71 and 76-81 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13, 18-19, 21-22, 25-29, 31-47, 76-77, and 80 of copending Application No. 09/435576. Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass similar subject matter.

Instant application is directed to a controlled release oral solid dosage form for the reduction of serum cholesterol levels, containing lovastatin and a controlled release carrier wherein said dosage form has certain functional limitations upon consumption of the dosage form.

Co-pending application is directed to a controlled release oral solid dosage form for the reduction of serum cholesterol levels, containing alkyl ester of hydroxyl substituted napthalenes and a controlled release carrier wherein said dosage form has certain functional limitations upon consumption of the dosage form. Lovastatin is claimed in an independent claim.

Although both instant application and co-pending application are directed to different functional limitations, both applications are claiming the same type of dosage form, containing the same active agent, and are used for the same purpose. Furthermore, the instant application and co-pending application have a genus-species relationship wherein instant application recites the species, which falls within the scope of co-pending application recitation of the generic HMG-CO-Reductase Inhibitors. Therefore, the instant application and co-pending application claims encompass similar subject matter with obvious modifications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

Gary L. Kunz

GARY KUNZ
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